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08/908,867

APPLICATION NUMBER	08/908,867	FILING DATE	08/08/97	FIRST NAMED APPLICANT	YOUNG	ATTY. DOCKET NO.	A 227/166
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HM21/0707

EXAMINER
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UNRAR 8	PAPER NUMBER
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1642  
1642

DATE MAILED: 07/07/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2/17/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

- ☒ Claim(s) 1-21 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-21 are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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1. Claims 52-66 are pending in the application and are currently under prosecution.
2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

**Group I.** Claims 1-11 and 20-21 are drawn to a method of beneficially regulating gastrointestinal motility, classified in Class 514, subclass 2.

**Group II.** Claim 12 is drawn to a method of treating postprandial dumping classified in Class 514, subclass 2.

**Group III.** Claims 13 and 16 are drawn to a method of treating postprandial hypoglycemia, classified in Class 514, subclass 2.

**Group IV.** Claims 13 and 14 are drawn to a method of treating postprandial hypoglycemia, classified in Class 514, subclass 2.

**Group V.** Claim 17 is drawn to a method of treating type 1 diabetes, classified in Class 514, subclass 2.

**Group VI.** Claim 18 is drawn to a method of treating impaired Glucose tolerance, classified in Class 514, subclass 2.

**Group VII.** Claim 19 is drawn to a method of treating ingestion of a toxin, classified in Class 514, subclass 2.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising molecules of different structure and function wherein the molecules are (a) exendin and (b) exendin

6. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising beneficial regulations of gastrointestinal motility with different mechanisms of action wherein the regulation comprises (a) reducing gastric motility (claim 2) and (b) delaying gastric emptying (claim 3).

7. Group I is further subject to election of a single disclosed species.

Claims 1-3 are generic to a plurality of disclosed patentably distinct species comprising molecules of different structure and function wherein the molecules are (a) exendin 3 (claim 4) and (b) exendin 4 (claim 5).

8. Group I is further subject to election of a single disclosed species.

Claims 11-3 and 6 is generic to a plurality of disclosed patentably distinct species comprising methods of diagnosis which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the methods are (a) radiological examination (claim 7) and (b) magnetic resonance imaging (claim 8).

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9. Group I is further subject to election of a single disclosed species.

Claims 1-3, 9 and 10 are generic to a plurality of disclosed patentably distinct species comprising gastrointestinal disorders with different etiologies and mechanisms wherein the disorders are (a) acute diverticulitis (claim 11), (b) disorder of the biliary tract (claim 11), © disorder of the Sphincter of Oddi (claim 11).

10. It is noted that claims 20 and 21 will be examined as they are drawn to the elected species.

11. Group II is further subject to election of a single disclosed species.

Claim 12 is generic to a plurality of disclosed patentably distinct species comprising molecules of different structure and function wherein the molecules are (a) exendin and (b) exendin agonist.

12. Group III is further subject to election of a single disclosed species.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising molecules of different structure and function wherein the molecules are (a) exendin and (b) exendin agonist.

13. Group IV is further subject to election of a single disclosed species.

Claims 13 and 14 are generic to a plurality of disclosed patentably distinct species comprising molecules of different structure and function wherein the molecules are (a) exendin and amylin (claims 13 and 14), (b) exendin and amylin agonist (claims 13-15), © exendin agonist and amylin (claims 13 and 14), (d) exendin agonist and amylin agonist.

14. Group V is further subject to election of a single disclosed species.

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Claim 17 is generic to a plurality of disclosed patentably distinct species comprising molecules of different structure and function wherein the molecules are (a) exendin and (b) exendin agonist.

15. Group VI is further subject to election of a single disclosed species.

Claim 18 is generic to a plurality of disclosed patentably distinct species comprising molecules of different structure and function wherein the molecules are (a) exendin and (b) exendin agonist.

16. Group VII is further subject to election of a single disclosed species.

Claim 19 is generic to a plurality of disclosed patentably distinct species comprising molecules of different structure and function wherein the molecules are (a) exendin and (b) exendin agonist.

17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R.

§ 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

20. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

21. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.8821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons(s) set forth on the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer from the date of this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821 (g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for

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response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the applicant and should be addressed to [lila.feisee@uspto.gov](mailto:lila.feisee@uspto.gov).

All internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of USC 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

June 30, 1998

A handwritten signature in black ink, appearing to read 'LILA FEISEE', with a stylized, flowing script.

LILA FEISEE  
SUPERVISORY PATENT EXAMINER

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING  
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7.

Other: \_\_\_\_\_

**Applicant must provide:**

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123

For CRF submission help, call (703) 308-4212

For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.